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Actavis Totowa LLC

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

In re:
OXYCONTIN ANTITRUST LITIGATION

04-md-1603 (SHS)

This document relates to:

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC., and
PURDUE PHARMACEUTICALS L.P.,

Plaintiffs and Counterclaim Defendants,

v.

KV PHARMACEUTICAL COMPANY and
ACTAVIS TOTOWA LLC,

Defendants and Counterclaim Plaintiffs,

v.

THE PURDUE FREDERICK COMPANY,
THE PURDUE PHARMA COMPANY, and
EUROCELTIQUE S.A.,

Counterclaim Defendants.

Civil Action No.: 1:07 Civ. 03972
(SHS)

**ACTAVIS TOTOWA LLC'S
MEMORANDUM OF LAW IN SUPPORT OF ITS
MOTION TO LIFT THE STAY OF THE PATENT ISSUES**

In light of the Court's January 7, 2008 Opinion and Order resolving the inequitable conduct issue remanded by the Federal Circuit Court of Appeals, Actavis Totowa LLC ("Actavis") requests that the stay of the infringement claims of plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. (collectively "Purdue") and the invalidity claims of the generic defendants (Actavis, KV Pharmaceutical Company ("KV") and Mallinckrodt Inc. ("Mallinckrodt")) be lifted. In its July 27, 2007 Order (the "Scheduling Order"), the Court stayed these claims in order to first address the inequitable conduct issue that was remanded by the Federal Circuit Court of Appeals in Purdue Pharma L.P. v. Endo Pharmaceuticals Inc., 438 F.3d 1123 (Fed. Cir. 2006). Now that the inequitable conduct issue has been resolved, Actavis requests that the remaining patent issues be allowed to proceed to an expeditious resolution.¹

BACKGROUND

Purdue originally filed suit against Mallinckrodt in November 2006 and against Actavis and KV in January 2007. After some delay in having the suit against Actavis and KV transferred to this Court from the United States District Court for the District of Delaware by the Judicial Panel on Multidistrict Litigation, a joint scheduling conference was held on July 12, 2007 in order to resolve the various proposals put forth by the parties on how to proceed. Specifically, KV and Mallinckrodt suggested that the Court first resolve the inequitable conduct issue that was remanded by the Federal Circuit while staying the remainder of the case. Actavis, on the other hand, requested that the patent infringement and invalidity issues be allowed to proceed alongside the inequitable conduct issues. (See Conference Transcript at 18-19.) After evaluating the various proposals, the Court issued an order staying infringement and invalidity issues in

¹ As explained in Actavis' March 7, 2008 Opposition to the Direct Purchaser Class Plaintiffs' and Non-Class Plaintiffs' Motion to Lift the Stay, the antitrust claims should continue to be stayed in order to allow the patent issues to be efficiently resolved.

favor of focusing on the issue of inequitable conduct first. (See July 27, 2007 Scheduling Order at ¶ 2.)

The inequitable conduct issue concerning the patents in suit was resolved by the Court's January 7, 2008 Opinion and Order. On January 8, 2008, Actavis requested by letter that the stay of the infringement and invalidity issues be lifted and that a conference be held to discuss an appropriate schedule to resolve the patent issues. On February 12, 2008, Purdue filed a similar request for a status conference to discuss how to proceed on the patent issues. In its letter, Purdue also reminded the Court about the 30-month stays that were in place, which prevent FDA from approving the generic products of Actavis and KV until at least June 2009 or an earlier court decision finding the '042 patent invalid or not infringed. The requests from Actavis and Purdue are currently pending before the Court.

ARGUMENT

The initial reason for the stay of the patent infringement and invalidity issues evaporated when the Court issued its January 7, 2008 Opinion and Order. At this time, there is no reason to keep the stay of the remaining patent issues in place. Lifting the stay and expediting a resolution of the remaining patent issues is consistent with the purpose of the Hatch-Waxman Act; namely, to "get generic drugs into the hands of patients at reasonable prices – fast." In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991). Indeed, the Court recognized during the July 12, 2007 scheduling conference that it is "under statutory obligation here to move these Hatch-Waxman cases." (Conference Transcript at 5-6.)

Moreover, when Purdue initiated its patent infringement actions against Actavis and KV, FDA approval of their generic versions of OxyContin[®] was automatically stayed for 30 months or an earlier court decision finding the patents invalid or not infringed. 21 U.S.C.

§ 355(j)(5)(B)(iii). According to Purdue's February 12, 2008 letter to the Court, the 30 month stays begin to expire in June 2009. Because an earlier decision by this Court finding the '042 patent invalid or not infringed will terminate the 30 month stay and allow FDA to approve the generic products, the Court should expedite a resolution of the patent issues. Lifting the stay will ensure that the parties return to the remaining patent issues, which is consistent with the Hatch-Waxman mandate that the parties "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

CONCLUSION

For the foregoing reasons, Actavis respectfully requests that the Court enter an Order lifting the stay of the patent infringement and invalidity issues and setting a scheduling conference in order to adopt a schedule that allows for the expeditious resolution of the remaining patent issues.

Dated: March 14, 2008

Respectfully submitted,

By: /s/ Chad A. Landmon
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